K002646

OCT 2 6 2000

DIAGNOSTICS

Premarket Notification [510(k)] Summary

Company: ABX Diagnostics, Inc.
34 Bunsen Drive
Irvine, CA 92618
Phone: (949) 453-0500 FAX: (949) 453-0600

Contact Person: Bruce H. Davis, MD
Phone: (207) 842-7914 FAX: (207) 761-2130
Date Prepared: July 10, 2000

Trade/Proprietary Name: **ABX MICROS CRP**

Common or Usual Name: Automated cell counter and
Automated differential cell counter

Classification Name: Automated cell counter (864.5200) and
Automated differential cell counter (864.5220)

Product Code: GKZ for the hematology analyzer
DCK for the C-reactive protein (CRP) test system

Substantial Equivalence:

The **ABX MICROS CRP** is substantially equivalent to the following two predicate devices:

- Bayer ADVIA 60
- Roche COBAS INTEGRA C-Reactive Protein, Antigen, Antiserum, and Control

Description:

The **ABX MICROS CRP** is a benchtop clinical laboratory instrument which analyzes *in-vitro* samples of whole blood to provide complete blood count using principles of cytochemistry, focused flow impedance, and light scattering and C-reactive protein (CRP) measurement using principles of immunoturbidity.

DIAGNOSTICS

Indications for Use:

The **ABX MICROS CRP** is an open tube, automated (microprocessor controlled) hematology analyzer used for the *in vitro* diagnostic testing of whole blood specimens. The device operates in complete blood count (CBC) mode or in CBC + C- reactive protein (CRP) mode. Measurement of CRP aids in evaluation of the amount of injury to body tissues.

Comparison to Predicate Devices:

The **ABX MICROS CRP** is equivalent to the ADVIA 60 since both are automated hematology analyzers using whole blood to measure WBC, RBC, Hgb, Hct, MCV, MCHC, RDW, PLT, MPV and LYM, MON, GRA % & #. Both utilize the same principles of operation for measuring these parameters: cytochemistry, focused flow impedance, and light scattering. Both systems use the same reagents. The ABX MICROS CRP is equivalent to the cassette for the COBAS INTEGRA C-Reactive Protein assay since they have the same intended use with respect to CRP and utilize the same principle of operation (immunoturbidity). They differ in specimen used (ABX MICROS CRP uses whole blood and COBAS INTEGRA C-Reactive Protein uses serum or plasma) and design. In the ABX MICROS CRP, the CRP assay is integral to the design, it is simply another measurement in a blood panel. In the COBAS INTEGRA 700, the cassette COBAS INTEGRA C-Reactive Protein must be inserted into the device if the CRP function is used.

Discussion of Performance Data:

The determination of substantial equivalence is based on precision, linearity, stability and carry-over studies as well as an interprocedural correlation study. For the interprocedural correlation study, twenty-five clinical samples from normal patients and 75 clinical samples from patients with diseases in which CRP levels were likely to be elevated were tested with the **ABX MICROS CRP** and the COBAS INTEGRA 700 with COBAS C-Reactive Protein cassette.

Conclusions:

The data demonstrate that within-run, between-run, and between-day precision for the ABX MICROS CRP is acceptable. The assay is quite linear up to 20 mg/dL with a slight loss of linearity for undiluted samples at approximately 7-10 mg/dL. The carry-over is negligible. The results of the interprocedural study indicate that the ABX MICROS CRP assay is highly correlated with the COBAS INTEGRA CRP assay.

Prepared By: Patricia Amtower, Consultant, ProMedica International

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 6 2000

Bruce H. Davis, M.D.
Director of Medical Affairs
ABX Diagnostics, Inc.
34 Bunsen Drive
Irvine, California 92618

Re: K002646
Trade Name: ABX Micros CRP
Regulatory Class: II
Product Code: GKZ
Dated: August 24, 2000
Received: August 24, 2000

Dear Dr. Davis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002646

Device Name: **ABX MICROS CRP**

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CRFR 801.109)

Peter E Magnin

(Division Sign-Off)
Division of Clinical Laboratory Devices K002646
510(k) Number